PLACIDE study Case Report Form (CRF)

A multicentre, randomised, placebo controlled trial of lactic acid bacteria and bifidobacteria in the prevention of antibiotic-associated diarrhoea and *Clostridium difficile* diarrhoea in patients aged 65 years and over admitted to hospital and receiving antibiotics.

Front sheet: Check id details on each page and completeness of all data. Detach pages 1 and 2 and file in register before CRF goes to data entry clerk.

Study number issued at recruitment **:** **PLACIDE** | | | | |

While in the study the participant will be identified by this study number

Is the patient eligible? check inclusion / exclusion criteria (page 2) Y/N |

Patient details

Name

Hospital number Age

Address and post code

Telephone:

Home:	Work:
Mobile:	E mail:

Details of next of kin

Name

Relationship: Spouse-1; Son/daughter -2; Relative-3; Carer-4; Other-5 |

Address and post code

Telephone:

GP details

Name

Address and post Code

Telephone:

Date completed / / signed

PLACIDE study *Research number:* | | | | | *Patient initials:* |

Inclusion criteria*: code as Y / N

- Age ≥ 65 years
- One or more doses of antibiotic within last 7 days or starting antibiotic today
- Consultant approval for invitation to join study

Exclude if "No" to any of these questions

Exclusion criteria*: code as Y / N

- Diarrhoea now[1]
- Immunocompromised[2]
- Active inflammatory bowel disease[3]
- Prosthetic heart valve
- Suspected acute pancreatitis[4]
- Requires high dependency or intensive care[5]
- Known compromised gut blood supply[6]
- Naso-jejunal feeding tube *in situ*
- Adverse reaction to previous probiotics
- Continues on other live bacterial food preparations
- *C. difficile* in past 3 months

Exclude if "Yes" to any of these

1. 3 or more watery or loose stools (Bristol Stool Chart 5 - 7) in a 24 hour period.
2. Compromised immunity sufficient to require isolation and barrier nursing (e.g. disseminated cancer / chemotherapy, AIDS, known immunodeficiency disease)
3. Required specific treatment in past 12 months
4. Abdominal pain + serum amylase/lipase >3 ULN
5. Not admission just for observation (e.g. post cardiac surgery)
6. Disease, stenosis or thrombosis of mesenteric vessels or coeliac axis

***If in doubt, discuss with Project Manager or Research Clinician *before* recruitment**

Date completed | | / | | / | | signed

PLACIDE study *Research number:* | | | | | *Patient initials:* |

Data entry clerks: Enter the following data into the PLACIDE CRF database

Date person recruited into PLACIDE study | | / | | / | |

If assent, relationship to patient: _____(see previous)

Demography

Gender: Male-1; Female-2 |

DOB | | / | | / | |

Race: White-1; Black-2; Asian-3; Chinese-4; Other-5 and specify: |

Weight (kg) | | | . |

Average number cigarettes / day | |

Average number units alcohol / week* | |

*Approx units: 1 pint beer – 2; 1 standard glass wine – 2; small measure spirits – 1.

This admission

Date of hospital admission | | / | | / | |

Initial diagnosis / reason for admission

Admitted from home-1, residential care-2, other hospital-3, other -4 |

If other, details: ……..

Previous gastrointestinal surgery? Y / N |

If Yes – specify operation(s) done and year performed:

Co- morbidity (Y / N or 9 if not known):

Hypertension | Asthma | Diabetes |

COPD | Renal Disease | Irritable bowel syndrome |

Dementia or Alzheimer's disease | Other co-morbidity* |

*If Yes - specify:

Date completed | | / | | / | | signed

Other information

Current stool frequency / week | | stool consistency (Bristol chart) |

No. hospital admissions in last 8 weeks | | NGT *in situ* : Y / N |

Live bacteria consumed in last 2 weeks* |

* includes live yogurts (e.g. Actimil, Yakult), probiotics bought from health food shops, over internet

STUDY intervention

Day 1 is the first day that the person *had the opportunity* to take the study intervention and is either the same day as the recruitment day or the next day.

Day 1 date | | / | | / | |

Start time of study intervention (nearest hour; 24 hour clock)* | |

*record 99 if not known; 88 if not taken

End of study summary : Complete at the end of follow-up

Final classification of participant |

No diarrhoea-1; AAD-2; *C. difficile* diarrhoea-3; other cause of diarrhoea-4; died-5; withdrawn-6.

Outcome date (death, withdrawal, end of FU): | | | | | |

Date of hospital discharge: | | / | | / | |

Discharge and outcome dates same if participant dies or is withdrawn in hospital

If withdrawn: |

High dependency or ITU care-1; pancreatitis-2; bowel ischaemia-3; other – 4 and details:

Notes:

Please check that all data is accurate and complete. Then submit form to Data Manager for checking prior to data entry

Date completed | | / | | / | | signed |

Medication record: Antibiotics

Record details of any antibiotics (including single doses) that the person has taken in the 8 weeks before recruitment until the end of follow-up.

- Record as much information as possible (e.g. "middle November" = 15/11/xx)
- Route: Oral/NGT = 1; IV/IM = 2; other = 3
- Record dates as DD/MM/YY; record 88/88/88 if on-going at end of follow-up; 99/99/99 if not known
- Check that the information is complete at the end of follow-up

Antibiotic 1: | Route | Dose (mg) | No. doses/day |

Indication: |

Start date | / / | Stop date: | / / |

Antibiotic 2: | Route | Dose (mg) | No. doses/day |

Indication: |

Start date | / / | Stop date: | / / |

Antibiotic 3: | Route | Dose (mg) | No. doses/day |

Indication: |

Start date | / / | Stop date: | / / |

Antibiotic 4: | Route | Dose (mg) | No. doses/day |

Indication: |

Start date | / / | Stop date: | / / |

Antibiotic 5: | Route | Dose (mg) | No. doses/day |

Indication: |

Start date | / / | Stop date: | / / |

Antibiotic 6: | Route | Dose (mg) | No. doses/day |

Indication: |

Start date | / / | Stop date: | / / |

Date completed | / / | signed |

Antibiotic 7: Route Dose (mg) No. doses/day

Indication:

Start date / / Stop date: / /

Antibiotic 8: Route Dose (mg) No. doses/day

Indication:

Start date / / Stop date: / /

Antibiotic 9: Route Dose (mg) No. doses/day

Indication:

Start date / / Stop date: / /

Medication record: other drugs being taken at recruitment

Enter Y, N or 9 for don't know

- Proton Pump inhibitor[1]
- Antacids
- Anti-hypertensives
- Oral hypoglycaemic agents
- Insulin
- H_2 blockers[2]
- ACE inhibitors
- Aspirin (used most days)
- NSAIDS (used most days)
- *Commercial feed + prebiotic

*If Y, name:

1. Examples are: lanzoprazole, omeperazole.
2. Examples are: ranitidine, cimetidine, zantac.